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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/600,130 | 05/14/2001 | Keith H.S. Campbell | 105434.105001 | 8898 |

7590 01/11/2005
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Atlanta, GA 30303

EXAMINER

WOITACH, JOSEPH T

| | |
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| ART UNIT | PAPER NUMBER |
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1632

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/600,130

Applicant(s)

CAMPBELL, KEITH H.S.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 18, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-47, 49, 50, 56-63, 66-76 and 83-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42-47, 49, 50, 56-63, 66-76 and 80-89 is/are allowed.
- 6) ☒ Claim(s) 80-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 July 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a national stage filing of PCT/GB00/00086, filed January 13, 2000 (amended July 12, 2000 and October 13, 2000), which claims benefit to provisional application 60/130,546 filed April 22, 1999 and claims benefit to foreign application 9900734.6 filed January 13, 1999 in Great Britain.

Applicants amendment filed October 18, 2004, has been received and entered. Claims 1-41, 48, 51-55, 64, 65, 77-79 have been canceled. Claims 42, 49, 50, 69, 72, 74, 80-82 have been amended. Claims 89 has been added. Claims 42-47, 49, 50, 56-63, 66-76, 80-89 are pending and currently under examination.

Election/Restriction

Applicant's election without traverse of Group I was acknowledged. Newly added claim 89 has a different preamble than that set forth in the original claims, however the method steps are the same, therefore will be examined with the instantly elected invention. In addition, it is noted that the election of species was withdrawn.

Claims 42-47, 49, 50, 56-63, 66-76, 80-89 are under examination to the extent they encompass the elected invention of a method of producing an animal embryo comprising passing a diploid nuclear donor through a first recipient oocyte, then into a second oocyte or zygote, the embryo produced by this method, a cell line produced from the embryo and a method of producing an animal from said embryo.

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Claim Objections

Claim 42 objected to because it did not encompass the elected invention of using of using a diploid cell is withdrawn. .

Amendments to the claim has obviated the objection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 77-79 previously rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn.

Cancellation of the claims has rendered the rejection moot.

Claims 80-82 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn.

Amendments to the claims to recite an isolated ungulate embryo has obviated the basis of the rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 42-47, 49, 50, 56-63, 66-76, 80-88 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,525,243 B1 is withdrawn.

Applicant argues that the teaching of '243 can be differentiated from that instantly claimed because while each teach serial transplantation the instant claims are drawn to serial transplantation from one oocyte to a second, while '243 teach the growth and expansion of the first oocyte then a transfer to a second oocyte. The teachings of '243 provide a means to increase the efficiency of cloning by clonally expanding the first oocyte increasing the number of embryonic cells for the second transfer. There is no specific teaching nor suggestion that the first transfer should or could be limited to re-programming only in the oocyte without further expansion.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

Claims 80-82 rejected under 35 U.S.C. 102(b) as being anticipated by Thomson (US Patent 5,843,780 A) is withdrawn.

The amendment to the claims to recite ungulate embryo has differentiated the claimed invention from that disclosed by Thomson.

Claims 42-47, 49, 50, 56-63, 66-76, 83-88 rejected under 35 U.S.C. 102(e) as being anticipated by Stockman Campbell *et al.* (US Patent 6,525,243 B1) is withdrawn.

As discussed above in remarks regarding the rejection made under obvious double patenting, the instantly claimed methods are distinguished from those claimed and generally taught in '243 because the instant claims require that the serial transfer be performed between oocytes, and that the first oocyte is not allowed to divide and expand into an embryo.

However, claims 80-82 stand rejected under 35 U.S.C. 102(e) as being anticipated by Stockman Campbell *et al.* As noted previously, Stockman Campbell *et al.* teach a method of nuclear transfer comprising the transfer of a somatic cell into a recipient oocyte. Stockman Campbell *et al.* provide detailed guidance for the timing of the insertion of the nuclear material into the oocyte, activation and general methodology to culture the resulting nuclear transfer unit into a viable embryo and ultimately cloned animal (see claim 1). Stockman Campbell *et al.* teach that the method can be used for any animal anticipating the specific species set forth in dependent claims. Thus, Stockman Campbell *et al.* provide each of the specific method steps set forth in the claims. It is noted that claims 80-82 are drawn to a product produced by the process

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of claim 42, which is different from the method of '243 however where, as here, the claimed and prior art products are identical or substantially identical, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). In this case '243 teach the production of undifferentiated embryonic stem cell lines and cell populations obtained from an ungulate embryo. As discussed in the present specification and Applicant's arguments, the present methods provide a method resulting in increased efficiency than methods of the prior art, however this does alter or distinguish the final products produced by the methods.

Claims 42-47, 49, 50, 56-63, 66-76, 80-89 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter is withdrawn.

Applicants arguments that the claimed invention is different from that discussed in '243 and that Campbell is the inventor of the instantly claimed methods addresses the rejection of record.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-47, 49, 50, 56-63, 66-76, 80-88 rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell *et al.* (WO 97/07669), Gurdon (J Cell Sci 4 :287-318, 1986) and Stice *et al.* (Biol of Reprod, 48 :715-719,1993) is withdrawn.

Applicant argues that Campbell *et al.* (WO 97/07669) provides the same teaching that '243 provides and that the instantly claimed method can be distinguished from that taught by either Campbell or Gurdon in the cited prior art because there is no specific teaching or motivation to practice the method of serial transfer from one oocyte to the next without growth and expansion of the first oocyte.

Examiner agrees that the methods in the prior art fail to teach the instantly claimed method. While there is some general motivation to use an embryo at very early stages, in particular in experiments using the mouse, the embryo of an ungulate is different from that of a mouse. Unlike the mouse, the cells of an embryo of an ungulate are more totipotent and are individually capable of giving rise to a clone when split at later stages such as the 4, 8 and 16 cell stages depending on the ungulate. Therefore, in ungulates the observations provided in the mouse model would not necessarily apply or be required since the embryonic cells of an ungulate embryo are totipotent at later stages of development.

Conclusion

Claims 80-82 are rejected. Claims 42-47, 49, 50, 56-63, 66-76, 83-89 are allowed because while the prior art teaches methods of serial transplantation in nuclear transfer methodology, it fails to specifically teach or provide the motivation to the serial transplantation between oocytes that are not allowed to expand to increase the clonal number of donor cells.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

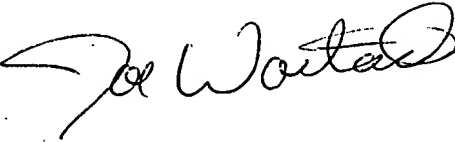
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach


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